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BIOLOGICAL THREATS: A MATTER OF BALANCE

Summary

- The bioterrorist threat has been greatly exaggerated.
- New bioweapons assessments are needed that take into account the complex set of social and technical issues that shape bioweapons development and use by state and non-state actors, and that focus on more plausible threats than the worst-case scenarios that have largely driven discussion to date.
- Continuing to emphasize and spend billions of dollars on measures to specifically counter bioterrorist threat scenarios distorts our national understanding of the important issues in public health, and diverts scarce scientific talent and resources away from more pressing public health and natural disease threats.
- While it has been argued that spin-offs from biodefense programs contribute to countering natural diseases, the converse is more likely: direct targeting of effort and expenditure on natural disease threats would provide much greater public health benefit, and spin-offs from these programs would significantly strengthen resistance to bioterrorism.
- Bioterrorist threats need to be seen and addressed within a wider public health context--as just one of the many possible ways in which infectious agents may harm human, animal, and plant health.

How Serious is the Bioterrorist Threat?

- Beginning in the early 1990s, an increasing amount was written about the threat of bioterrorism. Prior to 2001 most examples of “bioterrorism” were in fact hoaxes or were only tenuously related to actual threats, with the single exception of the use of *Salmonella* to contaminate salad bars in Oregon in 1984. Much was made of the Japanese group Aum Shinrykio’s unsuccessful attempts to use anthrax and botulinum toxin without drawing the simple and obvious lesson that achieving success in such attempts is difficult. The 2001 anthrax letters were seen as validating large scale and catastrophic threat scenarios, despite the very real difficulties that isolated individuals or small groups would have had in making such material. By the time the source of those letters was identified in August 2008 as a government laboratory with capabilities vastly in excess of those of any terrorist organization, biodefense programs costing tens of billions of dollars were already established, producing a potent and vocal constituency for continued and increased funding.
- Offensive, including terrorist, use of biological agents presents major technical problems. This is why the Soviet Union, United States, United Kingdom and others needed to spend vast sums for decades in order to research and develop biological weapons. Even then the

results were considered an unreliable form of warfare, and there was little opposition to their elimination by international agreement (indeed the US unilaterally eliminated its biological weapons stockpiles).

- Fictional bioterrorism exercises such as Atlantic Storm and Dark Winter routinely used unrealistic values for critical parameters and were unrealizable by putative perpetrators. They tended to gloss over the very real problems involved in acquiring, growing and disseminating smallpox virus on a sufficient scale to represent a major threat. They also posited unreasonable assumptions about issues such as the rate of disease spread, which skewed the outcomes towards inflated and unlikely results.
- The effects of using biological materials, whether on a large scale or a smaller terrorist scale, are highly uncertain. Although the 2001 anthrax letters created panic and had a significant economic impact, the number of deaths and serious illnesses was very small.
- Existing bioweapons assessments focus on a narrow set of assumptions about potential adversaries and their technical capabilities. New bioweapons threat assessments are needed that take into account the more complex set of social and technical issues that shape bioweapons capabilities of state and non-state actors and that critically examine existing assumptions.

How Effective Are Bioterrorism Counter Measures?

- Much time, effort and money has been spent since 2001 trying to identify possible threats, create detection capabilities in government facilities and public spaces, and enact measures to prevent dangerous agents from falling into the wrong hands. Yet, threat scenarios are speculative and rely on too many unjustified assumptions, thus providing poor policy guidance. Detection systems continue to suffer many defects of sensitivity and specificity that so far make them unreliable as triggers for immediate countermeasures. And the enormous expansion of high-containment laboratories has greatly increased the numbers of people with access to dangerous pathogens and toxins, ironically increasing the likelihood of an attack by a rogue insider.
- In addition, agencies and programs have been set up at great expense, with the aim of having available stocks of vaccines against potential bioweapons agents. Many questions remain about these programs with respect to vaccine efficacy, safety, shelf life and the ability to perform mass immunizations at short notice. Until these issues are resolved the effectiveness of vaccines as countermeasures remains in doubt.
- Countermeasures effective after exposure to anthrax and the smallpox virus, the bioterrorist threat agents of greatest concern, have been developed and stockpiled—antibiotics for anthrax and a vaccine for smallpox. Efforts to accumulate stockpiles of more novel therapeutics, or ones targeted to even less likely bioterrorist threats, are not cost-effective unless they would also serve clear public health goals.
- The actual dollar costs of responding to the perceived bioterrorism threat includes creating new agencies and programs, funding research & development into threat evaluation, detection, diagnosis, prophylaxis and treatments. These costs approach \$60 billion since FY 2001 and continue to rise. Of this, roughly \$15 billion has gone to state and local public health capacity building, hospital preparedness, and other efforts aimed at directly strengthening public health.

- There are additional opportunity costs that are much harder to quantify: the diversion of technical, scientific and administrative talent away from more real and immediate infectious disease and other public health problems. For example the amount of research being conducted on anthrax (of which there are only a handful of cases per year in the US) has skyrocketed since 2001, due largely to the attraction of scientists away from work on other diseases of greater public health importance. Biomedical research is expensive and requires substantial levels of funding; accordingly, funding decisions made for political purposes can easily distort the direction of scientific effort into less useful although still scientifically interesting avenues.
- These bioterrorism-specific programs are unnecessary and inefficient if the bioterrorist threat has been exaggerated or overestimated, and they divert scarce resources from much more pressing public health threats.

What Is The Impact On Public Health?

- To put this in perspective, since 2000 bioterrorism has killed 5 Americans. In the same time period, influenza-related deaths alone have likely exceeded 300,000 based on CDC estimates, and other natural infectious diseases have killed hundreds of thousands more. Annual US morbidity & mortality figures from AIDS (14,000 deaths), opportunistic infections such as MRSA (19,000 deaths/year) and *C. difficile* (350,000 infections and up to 20,000 deaths) speak to unmet and pressing public health need.
- Consequently the threat of bioterrorism, which does exist but which is almost certainly minor, needs to be seen as only one element in the wider and larger public health war on infectious diseases.
- While deaths and morbidity from these and other infectious diseases are unlikely to be entirely eliminated no matter how lavish the funding, modest increases in funding and effort (relative to that currently invested in bioterrorism prevention and mitigation) could greatly decrease their impact, and save orders of magnitude more lives than are likely to ever be lost in any plausible bioterrorist attack. There is a clear imbalance between funding for biodefense and funding for research on and prevention of natural infectious diseases.
- Diverting scarce resources, money, and scientific, medical and organizational talent away from the general public health effort to address the narrower bioterrorism issue is likely to be self-defeating in the longer term because:
 1. Highly specific threat predictions lead to specific countermeasures and mitigation strategies, many of which may be useless for everyday public health purposes, or even to counter a bioterrorist attack that differs from the threat assumed.
 2. Development and production of bioterrorism countermeasures may present uncertainties and risks compared with pharmaceuticals manufactured according to strict quality assurance standards, and are subject to constant scrutiny of their efficacy and safety through post-market research. Such is not the case with bioterrorism countermeasures, which would be used only rarely if at all.
 3. In comparison with investments in routine public health activities, countermeasures targeted against specific bioterrorism threats are unlikely to ever be used and their

manufacture, stockpiling and turnover thus represent a probable waste of scarce resources.

A Better Approach

- The public health problem of infectious diseases requires a more generic approach that addresses a variety of issues, including the following:
 1. Information about morbidity and mortality in terms of disease incidence and causes is critical in deciding which problems are most important and where intervention would provide the greatest benefit. A risk-based and data-driven approach should guide the allocation of scarce public health resources.
 2. The nation's epidemiological workforce must be adequate to investigate and address all public health issues: infectious disease outbreaks whether due to natural, deliberate, or accidental causes; chronic diseases; environmental health; consequences of nutritional and life-style choices; etc. Only by ensuring adequate staffing in all program areas will we build a sustainable public health infrastructure that can reliably provide adequate surge capacity in the event of a large-scale emergency.
 3. Animal disease epidemiology capability needs to be enhanced. This would improve the ability rapidly to detect and diagnose not only animal, but also zoonotic infections. Such enhanced capability would provide both a defense against natural disease outbreaks as well as a capability for early recognition of a bioterrorist threat originating in the animal population.
 4. Effective, ongoing training for epidemiologists, which has reached a plateau or has even been reduced since 2004, is essential.
 5. Provision of the basic tools necessary to support routine public health surveillance and epidemiology - including skilled personnel, public health laboratories, and data collection, management and analytic systems - are also critical. In this respect, public health preparedness funding, increased out of concern about terrorism in general and bioterrorism in particular, has been important and needs to be maintained and enhanced.
 6. Disaster preparedness needs to be improved—the ability to respond rapidly and effectively to an event that produces a large number of casualties needing hospitalization or sanitary burial is common to handling large natural outbreaks of infectious disease, a bioterrorism event, or a natural disaster such as earthquake or tsunami.
 7. Research is a key component of any program to improve public health and by extension the ability to deal with deliberately created outbreaks. The most obvious areas of need are in new antibiotics and antivirals for emerging or established diseases that cause significant mortality or morbidity. The role of vaccines in dealing with the bioterrorism problem is more controversial since vaccines are highly disease-specific (often even strain-specific), usually need to be given prior to exposure, tend to have a limited shelf life, and suffer from a problem of public acceptability. Research into immune system stimulation and enhancement which could have wide application may be a more fruitful investment.

8. Measures that enhance access by more people to preventive healthcare are likely to strengthen individual resistance to disease and improve early detection and effective treatment and containment of disease outbreaks.
- Fundamentally, improving the capability to respond to natural disease outbreaks, which currently present the major problem, almost automatically improves the capability to deal with any bioterrorist attack.